Exhibit G-2

McGartland Law Firm, PLLC
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Meshbesher & Spence, Ltd.
Michael Hingle & Associates
Morgan & Morgan
Murray Law Firm
Neal Elliott, Jr.
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The Miller Firm, LLC
The Olinde Firm LLC
The Ruth Law Team
Torhoerman Law, LLC
Tully Law Firm
Whitfield Bryson & Mason LLP
Zimmerman Reed, LLP

EXHIBIT D

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Scott Augustine, M.D.

State of Minnesota
County of Hennepin

Affidavit Under Oath:

To Whom It May Concern:

We, the undersigned, are all former engineers of Arizant, Inc., the company that manufactures Bair Hugger®. A majority of us worked specifically on Bair Hugger models 505 and 750 forced air warming blowers. Collectively, we are the listed inventors on more than 100 patents held by Arizant, Inc.

In our opinion there is no practical way to clean and decontaminate the air-flow path of forced air warming systems.

In designing the Bair Hugger blowers, the following assumptions were made:

1. That the 0.2 micron inlet filter (which is not a HEPA filter) was adequate to filter the already clean air of the operating theatre, and
2. That any pathogenic organisms entering the blower would not survive the warm, dry environment inside the blower.

With the emergence of air-borne superbugs, these assumptions are no longer adequate.

- The inlet filtration of Bair Hugger blowers does not prevent contamination. The majority of blowers that we have cultured were contaminated with bacteria.
- Some forced air blowers emit large numbers of 0.3-0.5 micron particles. We have measured up to 50 million particles per hour blowing from the hoses.
- The warm, dry interior of forced air blowers does not kill all pathogens. According to published literature, many of the most worrisome organisms such as MRSA and Acinetobacter remain viable for extended periods in dry environments and have been cultured from forced air blowers.

Keith Leland

Randy Arnold

Scott Entenman

Mark Albrecht

Andreas Deibel

Subscribed and sworn to before me, this 16th day of July, 2008.

Susan Elaine Schaefer
[signature of Notary]

(SEAL)

Susan Schaefer

My commission expires: January 31, 2010.

SUSAN ELAINE SCHAEFER
Notary Public-State of Minnesota
My Commission Expires
January 31, 2010

Blowing Air Is Risky

...now there's an [air-free] alternative.

"RESERVOIRS OF INFECTION"

Recent studies show that the air-flow paths of Bair Hugger®[1] blowers are frequently contaminated with bacteria.[2,3] These units blow many millions of germ-sized particles into the operating theatre each hour. No wonder a Department of Public Health in the U.S. called Bair Hugger units **"reservoirs of infection."**[5]

Contaminated Air is Blowing from the Unit

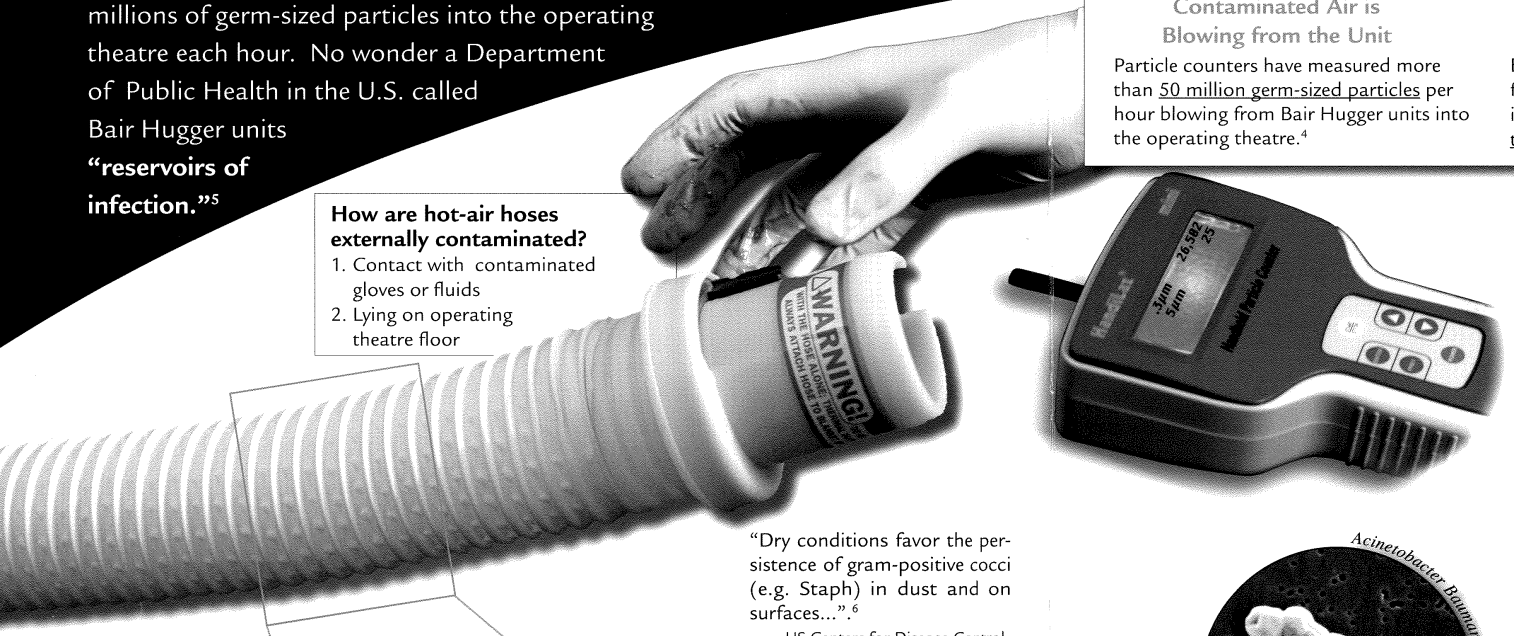
Particle counters have measured more than 50 million germ-sized particles per hour blowing from Bair Hugger units into the operating theatre.[4]

Fifty million particles? Where do they come from?

Blowers suck in clean air and pass it through a .2 micron filter—and still they blow millions of germ-sized particles into the operating theatre. Therefore, most of these particles must be originating from *inside* the blower and hose.

How are hot-air hoses externally contaminated?

1. Contact with contaminated gloves or fluids
2. Lying on operating theatre floor



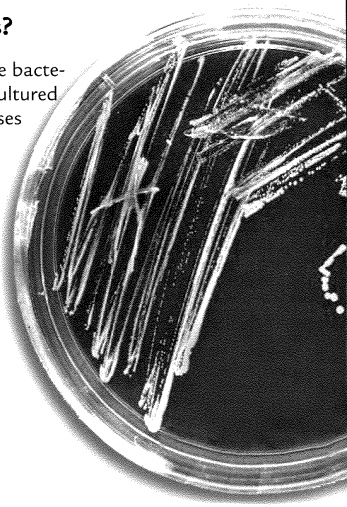
"Dry conditions favor the persistence of gram-positive cocci (e.g. Staph) in dust and on surfaces...".[6]

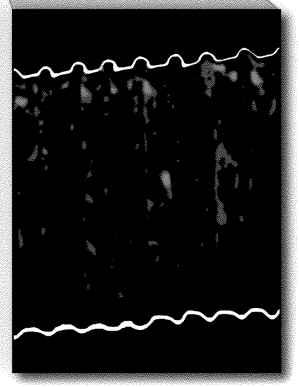
-US Centers for Disease Control

What are these 50 million particles?

Not all of the particles are bacteria, but bacteria can be cultured from both the air and hoses of many hot-air warming units. There should not be any particles, much less germs, blowing from the hose.

Germ colonies can be cultured by swabbing various locations within the unit or hose, or even by impacting the air blowing from the hose onto a culture plate.[3]





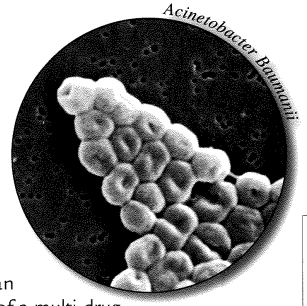
The hose above, carefully wiped with a disinfectant, appears to be clean...it isn't!

A crime scene forensic tool such as Luminol (a chemiluminescent compound that glows blue in the presence of trace blood), clearly shows widespread residual blood in the corrugations of this apparently clean hose.

Can hot-air hoses be cleaned? NO!

Routine wiping does not remove contaminants from the valleys of the hose. The creases within the 180 corrugations of a 7-foot hose are nearly impossible to clean.

All non-disposable equipment in the operating theatre must be cleaned—especially after exposure to blood, bacteria, and bodily fluids. Non-cleanable equipment is simply unacceptable.



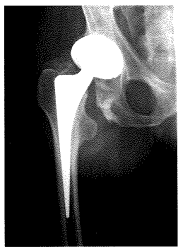
Infection Control and Hospital Epidemiology reported an outbreak of a multi-drug resistant *Acinetobacter* that was traced directly to the inside of a Bair Hugger machine.[2]

Despite reports such as this, the manufacturer does not offer a protocol for cleaning the insides of Bair Hugger blowers or hoses.[7]

Are airborne particles dangerous?

"The link between post-operative infection and theatre air quality has been well established."[8]

-UK Hospital Infection Society



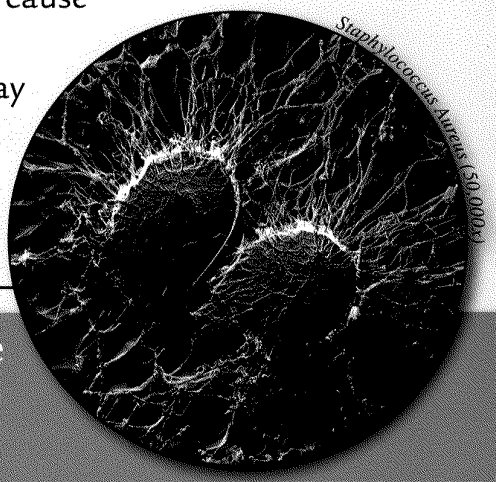
A single bacterium can infect a new joint implant.[9]

AIRBORNE CONTAMINATION
by blowing hot air

TO CONTAIN MRSA, AIRBORNE TRANSMISSION MUST BE PREVENTED

Leading experts in microbiology from Oxford, Cambridge and the University of London highlighted the MRSA problem in a letter to the *Times* of London. MRSA infections, said these experts, are far more likely to result from airborne transmission than from skin contact or equipment contact. **"Staphylococcus aureus [including MRSA] spreads on millions of tiny skin particles, shed by carriers, drifting in the air...." "To be truly effective, measures to contain MRSA must block airborne transmission."**[10]

- Blowing air through a contaminated warming unit may cause bacterial colonies to become airborne.
- Blowing air from a forced-air blanket across the skin may also cause skin particles to become airborne, spreading them into the operating theatre. Infectious agents—such as MRSA—can independently float in moving air or on "rafts" of dead skin particles.[11]



"We conclude that these warming devices* are a potential source of nosocomial infection."[3]

*Bair Hugger and Warm Touch®[1]

Visit
www.BlowingAirIsRisky.com
for more information

Introducing the [air-free] solution...

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The NEXT WAVE in Patient Warming

www.HotDogWarming.com

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Eden Prairie, MN 55344
952-465-3500 (phone) 952-465-3501 (fax)
www.augbiomed.com

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Rev A

As Hot Air Rises, So Does Risk

The rising hot air from forced-air warming blankets compromises the protective shield of Lam in ultra clean operating theatres.

Wednesday, October 14, 2009

Hot Air Disrupts the Protection of Laminar Flow

Watch the Video about Laminar Flow Disruption by Forced-air Warming

Please watch the video. It is honest, unaltered footage taken in a simulated OR of laminar flow ventilation being disrupted by forced-air warming. What you will see is physics at work.

The physics is simple: **heat rises!** After passing over the patient's skin and dropping near the dirty floor, the waste hot air rises--overpowering the ultra-clean downward air current of laminar flow-- and then, having cooled, falls into the surgical site.

Reducing surgical site infections (SSIs) is of the highest priority for hospitals, insurance companies, and national health initiatives. Not to mention patients and their families.

Providing an ultra clean surgical environment with laminar flow has become the standard of care because it helps reduce hospital acquired infections. A study cited by the Centers for Disease Control revealed **a reduction in SSIs from 3.4% to 1.6% merely as a result of laminar flow.**

Welcome.

The purpose of this blog show video evidence tal simulated OR of laminar ventilation being disrupt hot air from forced-air v We want to hear your c about hot air and its eff laminar flow. Your thou knowledge about curren future practices in patie warming are important

HotDog® conductive fal warming is an [air-free] warming alternative.

Hot Air Overpowers Downward Sterile Air Laminar Flow

Simulated OR shows ho destroying Laminar Flov simple physics. Watch t in the blog entry to see

Warming surgical patients, of course, is also the standard of care. Normothermic patients are far less likely to acquire a post-operative wound infection—64% less likely by one study (Mahoney, *AANA J*, 1999)—than those who aren't warmed. The device used to warm patients, however, should not increase the risk of bacterial contamination.

Fortunately, there is an [air-free] alternative. HotDog® conductive fabric warms as effectively as forced air, but is safe, eco-friendly, and much less expensive.

We encourage you to conduct the simple test detailed at the end of the video to prove that the forced-air exhaust heat rises in your operating room. Of course, it will. **Hot air always rises**.

We want to hear your comments about hot air and its effects on laminar flow. Your thoughts and knowledge are important to us.

Posted by HotDog Patient Warming at 1:50 PM

2 comments:

gibler said...

It is not possible to compare the thousands of cubicmeters of air circulated by the laminar air flow system to the few hundred liters of air from the warmair blower.
The effect of the forced air warming on the laminar air flow is less than opening a door into the operating room or like a person moving around close to the laminar air field.

February 20, 2010 8:27 AM

HotDog Patient Warming said...

gibler, thank you for your comment and your interest in the topic. You are correct that the protection of laminar flow is fragile and there are other factors such as people in the flow that are capable of disrupting it. However, research shows that the main reason that forced air warming (FAW) disrupts laminar flow is the waste heat and this disruption is relatively independent of the volume of the waste air. Physics dictates that heated air will always rise. Because the waste air from FAW is warm with 800-1000 watts of waste heat, it rises along the sides of the operating table and easily penetrates the downward traveling laminar flow air, despite the difference in air volume. If the rising warm air is contaminated with bacteria from the blower, the patient or from air resident near the floor, it is obvious that this contaminated air should never end up in the sterile field. However, research shows that in the presence of FAW, the

Given this informatio concerned are you ab contamination?

- ◯ Very concerned about cont
- ◯ Somewhat concerned
- ◯ Indifferent
- ◯ Not concerned about contar

Vote Show results

Votes so far: 16
Days left to vote: 273

Blog Archive

▼ 2009 (1)
▼ October (1)
Hot Air Disrupts th Protection of Lan

contaminated air from the floor clearly ends up in the sterile field above the wound in relatively high concentrations.

Research also shows that a person standing beside the operating table within the laminar air flow has about the same impact on particle counts in the sterile field that FAW alone has. However, the presence of both FAW and a person beside the table further increases particulate counts over the wound by a factor of 10! The person disrupts the laminar flow allowing the warm air to rise into the sterile field even more efficiently.

To answer your comment, forced-air warming clearly causes contamination of the sterile field over the wound with particles originating near the floor, despite the "protection" of laminar air flow. The contamination of the sterile field by FAW is even more severe in the presence of other laminar flow disrupting variables such as a surgeon standing by the table. There are more studies forthcoming.
Thank you for posting.

February 22, 2010 4:38 PM

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MedWatch Report

B.5.

Introduction

I am a Board Certified Anesthesiologist with special training and interest in cardiac and pediatric anesthesiology. I spent many years on the academic faculty at the University of Minnesota and have recently moved to private practice. As a practicing anesthesiologist—as well as a clinical researcher—I have observed numerous problems with forced-air warming systems ("FAW") that I believe put patients at risk. Specifically, I have studied Bair Hugger® FAW systems manufactured by Arizant, Inc. The results of much of this research have been disclosed to the executives at Arizant. Despite the fact that they have been aware of these problems for over two years, I have not seen any efforts on their part to correct the problems or to report the problems to either the authorities or to their customers.

Since I helped Arizant (Augustine Medical at that time) develop the intraoperative Bair Hugger product when it was introduced into the operating room about 20 years ago, I feel somewhat responsible for these newly discovered patient risks. I also find Arizant's behavior regarding the safety problems with their products - the fact that they appear to be in total denial regarding these problems-- to be very disturbing. That is why I am compelled to make this complaint to the FDA. This report summarizes my research and that of others as well as information that I have gathered from public sources and from industry.

I will address the following five risks to patient safety:

1. Bacterial contamination of FAW blowers—Multiple published studies, including my own, establish that the internal airflow paths of Bair Hugger blowers are routinely contaminated with multiple strains of pathogenic bacteria and that millions of particles per hour are commonly blown from the Bair Hugger systems into the sterile field.

2. Degradation of filtration—Despite representations by Arizant to the FDA and European regulators that the intake filters on its Bair Hugger blowers are HEPA (99.97% efficient), the efficiency of the filters has recently been reduced to 61.3%. As a consequence, the uncleanable interior of Bair Hugger blowers becomes more easily contaminated—and the contamination is blown into the surgical field.

3. Destruction of laminar flow protection by waste FAW heat—Contaminated hot air escapes from Bair Hugger blankets near the (non-sterile) operating room floor, mixes

with "dirty" air, then rises into the laminar flow currents that are intended to protect patients in ultra-clean surgeries. Not only is the laminar flow protection defeated, but the contaminated air also falls into the sterile field as it cools.

4. Breach of reprocessing standards—Arizant has refurbished thousands of Bair Hugger blowers. As noted above, these blowers are contaminated with pathogens. Arizant, however, does not sterilize—or even clean—the interiors of these blowers before placing them back into service. This creates the risk that pathogens may be transported from one clinical facility to another.

5. Failure to meet FDA reporting obligations—Upon becoming aware of the contamination of its systems, the consequences of the reduction of filter efficiency and the destruction of laminar flow protect caused by its systems, Arizant was required to report these issues to the FDA. It has not done so.

Background

A. Benefits of surgical normothermia

Because of the published research of D. Sessler, A. Kurz and others during the last twenty years, the benefits of maintaining surgical normothermia are undisputed. Normothermic patients spend fewer days in the ICU, require less blood, incur fewer morbid cardiac events, and –most importantly—suffer significantly fewer surgical infections than patients who become hypothermic during surgery. [1]

The benefits of normothermia have been acknowledged globally, and active patient warming has become a standard of care in many countries. In the United States, guidelines issued through the Surgical Care Improvement Project ("SCIP") strongly encourage "active warming" in any procedure lasting longer than one hour. [2] In the United Kingdom, guidelines promulgated by the National Institute of Clinical Excellence ("NICE") forbid beginning surgery unless the patient's temperature is at least 36°C. The patient may not be released to the ward until 36°C has been restored. [3]

B. Dominance of Bair Hugger therapy

Disposable forced-air warming blankets—and Bair Hugger therapy in particular—dominate the field. SCIP only recently added electrically conductive warming to its definition of "active warming," finally offering a practical alternative to FAW. According to IMS, however, Bair Hugger therapy commands a US market share of approximately 95%. Virtually all of the Bair Hugger blowers in use in the United States are owned by Arizant and "loaned" to hospitals in return for the purchase of disposable warming covers.

C. Early identification/discounting of risks

Concerns that blowing hot air around the operating theatre could risk patient safety were expressed early in the life of the technology. These concerns were summarily rejected and most clinicians now wrongly believe that the technology is safe. The rejection of the risk first occurred in an invited review of the technology by Sessler published in *Anesthesiology* in 2001. Sessler wrote:

> Surgeons are sometimes concerned that increasing air flow in operating rooms will increase contamination within surgical incisions. All forced-air warming include filters that essentially eliminate bacteria in the heated air. Furthermore, studies have demonstrated that the number of colony-forming units recovered from operating rooms is not increased by forced-air blowers. Finally, use of forced-air heating has been shown to reduce the incidence of surgical wound infection threefold by improving host defense. There is therefore no empirical support for the theory that forced-air heating increases infection risk. [4] (Emphasis added.)

Unfortunately, the key unsupported assertion made by Sessler —*"All forced-air warming include filters that essentially eliminate bacteria in the heated air."*— was untrue regarding Bair Hugger when the assertion was made. Since then, Bair Hugger filtration has gotten significantly worse. (See Sec. II, below) Additionally Sessler, like everyone else, was focused on the wrong issue – waste air, when the real issue is waste heat. Therefore, any of his opinions regarding the risks of FAW must be suspect

I. Bacterial Contamination of FAW blowers

A. Early research

In the late 1990s and early 2000s, several researchers raised issues regarding the safety of Bair Hugger blowers and demanded design changes. In 1997 M.S. Avidan cultured pathogen organisms from the air blown from 40% of forced-air blowers, stating as follows:

> We conclude that these warming devices are a potential source of nosocomial infection… (and suggesting that a) … microbial filter fitted to the nozzle of the hose could be incorporated into the design of the warmer to reduce the risk of contamination.[5]

In 2002 N. Baker and D, King wrote in a letter to the *Journal of Hospital Infection* that swabs from the exterior and interior of the blower all resulted in "heavy growth of bacteria." Air blowing from the end of the hose grew colonies of coagulase-negative *staphylococci, Bacillus spp., and Micrococcus spp.* "At present," they wrote, "there seems insufficient evidence to justify the routine use of forced air warming units as a intraoperative measure during ultra clean orthopaedic surgery." [6]

In 2003, M. Scherrer of the Institute for Environmental Medicine and Hospital Epidemiology, University Hospital of Freiburg, noted that "The air emitted from these (FAW) blankets also disturbs the ultra clean field and preliminary investigations have shown an increase of bacteria in the operating field when the warming system is on." [7]

In 2004, after unsuccessfully fighting outbreaks of *Acinetobacter baumannii* at Leiden University Medical Centre, infection control personnel isolated the bacteria to the filters of Bair Hugger blowers. After the pathogenic dust was removed, the outbreak ended, causing researchers to state:

> After…changing the filters of the Bear (sic) Hugger apparatus, the outbreak came to an end, suggesting that this apparatus was indeed the source of the outbreak. [8]

Dr. Suzanne Beavers, Epidemic Intelligence Service Officer of the Kentucky Department of Public Health, apparently reached a similar conclusion. In three separate publications (two speeches and a newsletter), Dr. Beavers identified Bair Huggers as a source of infectious outbreaks, repeatedly referring to them as "reservoirs of infection." (Annex A)

B. Recent research

1. In 2009, microbiologists from Stanford University essentially replicated the study done by Baker and King in 2002. They found that the internal air-flow paths of 12 of 29 Bair Hugger blowers cultured positive for pathogens and noted the recommendation that "an additional microbial filter be fitted to the distal end of the BH hose." (Annex B)

2. A 2010 study published in *Orthopedic Reviews* was authored by a team including myself and D. Leaper, the UK surgeon who chaired NICE's Surgical Site Infection Guidance Development Group. Prof. Leaper's team sampled 25 Bair Hugger blowers in their operating room environment. The results:

* Pathogenic bacteria were cultured from the internal air-flow paths of 94% of the blowers.

* 32% of the blowers tested were emitting internally generated airborne contamination in the size range of bacteria.

* 24% of the blowers tested were emitting "significant levels of internally generated airborne contamination."

The contamination, the authors stated, originated inside the blowers. The authors recommended adding a distal hose filter.[9]

3. Another study by Prof. Leaper's team has been accepted for publication in the *American Journal of Infection Control.* (Annex C) In that study, 52 Bair Hugger blowers were sampled in operating rooms. In summary:

* Micro-organisms were cultured from the internal air-flow paths of 92.3% of the blowers including *Staphylococcus aureus* (13.5%), coagulase negative *Staphylococcus aureus* (3.9%) and methcillin resistant *Staphylococcus aureus* (MRSA) (1.9%).

* 58% of the Bair Hugger blowers tested were found to be internally generating and emitting significant levels of airborne contaminants >0.3_μm in size (germ size), up to 35,272 particles per ft^3 of air (80 million particles per hour).

4. In a recent study (in submission for publication) by Dr. Michael Reed, an orthopedic surgeon in the United Kingdom, 23 Bair Hugger blowers were sampled in operating rooms. The findings:

* Micro-organisms were cultured from the internal air-flow paths of 100% of the blowers including coagulase negative *Staphylococcus aureus* (74%), mold (26%) and *Micrococci* (9%).

* 100% of the blowers were emitting internally generated particles >0.3 μm in size, up to 112,000 particles per ft^3 of air (300 million particles per hour).

* In the most contaminated blower, emitted particle count was 40 times greater than intake particle count.

5. In an abstract submitted to the American Academy of Orthopedic Surgeons 2011 annual meeting by Dr. M Reed, 75 Bair Hugger blowers in active use in 11 hospitals were cultured. Blowers with 93.8% efficient inlet filters were compared to blowers with 63.8% efficient inlet filters. The findings:

* Micro-organisms were cultured from the internal air-flow paths of 100% of the blowers with 63.8% efficient filters.

* Micro-organisms were cultured from the internal air-flow paths of 92% of the blowers with 93.8% efficient filters.

* There was a significant increase in common SSI pathogens (*s. aureus and s. epidermidis*) in the blowers with the lower 63.8% efficient filters (74% v 17%; $p<0.01$). (Annex D)

C. Consequences of contamination

Of course, it is not unusual for medical devices used during surgery to become contaminated. For that reason, the FDA and international regulators have developed strict rules regarding labeling, instructions for use and cleaning protocols that manufacturers must provide.

1. Violation of FDA regulations

Under FDA labeling regulations, 21 CFR 801, a device must have adequate directions, which include instructions on preparing a device for use. Instructions on how to reprocess (i.e., clean, and disinfect or sterilize) a reusable device are important steps in preparing a device for the next patient. Similarly, IEC 60601-1 deems labeling and instructions for use "a critical component of a medical device." An operator's manual is required to provide information on cleaning, preventive inspection, and maintenance to be performed by the user. In addition, the frequency of such maintenance must be specified. Manuals must provide complete instructions to ensure that routine maintenance can be performed safely.

The information provided by Arizant, however, does not even acknowledge the possibility that the internal air-flow path could be contaminated, much less provide instructions as to how the contamination can be abated. Cleaning instructions suggest merely that cleaning staff wipe the exterior of the blower with a damp cloth. [10]

2. Violation of United Kingdom regulations

(a) Health Act of 2006

As recently acknowledged by NICE, Bair Hugger is a two-part device: the paper/plastic blanket is disposable; the blower is reusable.[11] Reusable devices used in operating theaters are subject to special legal requirements in the UK. The Health Act of 2006 is unambiguous regarding such reusable devices:

Appendix 2, f. -- Decontamination of reusable medical devices

"Effective decontamination of reusable medical devices is essential."
"Reusable medical devices and other devices should be decontaminated in accordance with manufacturer's instructions and current guidelines."

Arizant's Bair Hugger system violates both requirements of the Health Act. The reusable portion of the system—the blower—cannot be effectively decontaminated between surgeries because the contamination is sealed inside the blower. As soon as the blower is activated, the contamination aerosolizes, exiting the blower and spreading into the sterile field.

(b) Medicines and Healthcare Products Regulatory Agency ("MHRA")

The manual of the Microbiology Advisory Committee, a group of experts reporting to the MHRA on disinfection and sterilization practices, confirms the requirement for the decontamination of reusable devices:

> Manufacturers of reusable medical devices are required by the Medical Devices Directive to supply clear written decontamination instructions, which should include appropriate cleaning, disinfection or sterilization methods. [12]

As noted, Arizant offers no instructions for decontamination whatsoever. The Bair Hugger Operating Manual suggests only that the outside of the blower box be wiped with a damp cloth. Having worked at more than a dozen hospitals, I have never seen any attempt to clean the internal airflow path or been informed of any such procedure.

3. Violation of EU Medical Devices Directive (MDD")

Medical devices in the UK and throughout the EU are governed by the MDD. Annex 1 of the MDD sets forth the Essential Requirements that each device must meet before achieving *Conformité Européenne* ("CE") and receiving the CE Mark. Essential Requirements include:

- The devices must be designed and manufactured in such a way that, when used under the conditions and purposes intended, they will not compromise the health or safety of patients, users or other personnel.
- Safety principles must be utilized for the design and construction, and they should include state-of-the-art technologies.
- The devices must meet all claimed performance criteria.
- The devices must continue to function as intended, without compromising safety or health, when subjected to normal conditions of use.

The Bair Hugger system fails to meet each of these Essential Requirements. When used as intended—in the operating theatre—the system compromises the safety of patients by spewing bacteria into the patients' open surgical wounds. By failing to include a hose-end filter to capture aerosolized bacteria, as researchers have demanded

since 1997, Arizant has ignored safety principles and avoided even basic technological protections. Under normal conditions of use, the blowers incubate pathogenic bacteria and blow the bacteria into the sterile field, clearly compromising the safety of patients.

Clause 13.6(h) of Annex I addresses issues identical to those addressed by the FDA in 21 CFR 801:

> If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses.

As noted above, instructions to wipe the outside of the blower with a damp cloth does not even purport to address the issue of internal contamination.

Section 8.1 of the MDD also addresses the issue:

> **8.1 Infection and Microbial Contamination**
>
> The devices and their manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties, the design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.

A system that incubates pathogens, blows those pathogens into the surgical site, and is impossible to clean is hardly "designed in such a way as to eliminate or reduce…the risk of infection…."

D. Culpability of Arizant

While Arizant may have been aware of the contamination risk created by Bair Hugger blowers even prior to October 2007, the facts were explicitly laid before Arizant executives at the annual meeting of the American Society of Anesthesiologists in San Francisco October 13-17, 2007. In a brochure and video presentation entitled "Blowing Air Is Risky," (Annex E) Arizant competitor Hot Dog International LLC publicly presented the following facts:

- A department of public health in the U.S. called Bair Hugger blowers "reservoirs of infection."
- Particle counters measured more than 50 million bacteria-sized particles per hours spewing from Bair Hugger blowers.

- An outbreak of multi-drug resistant *Acinetobacter* had been traced to the inside of Bair Hugger blowers, as reported in *Infection Control and Hospital Epidemiology*.
- Germ colonies could be cultured by swabbing inside Bair Hugger units and by impacting the air blown from the hose on a culture plate.

Copies of the brochure were provided to employees of Arizant during the meeting. (Affidavit of Dr. Scott Augustine, Annex F.)

In response to the Blowing Air Is Risky brochure, Arizant filed suit against Hot Dog International in Germany. In papers filed with the German court, Arizant repeatedly attacked the validity of the peer-reviewed, published research and asserted that any problem with contamination could be traced to the failure of Arizant's customers to change filters as required. (German documents are available upon request.) For example, Arizant alleged:

- Bair Hugger blowers were only a "possible" source of the *Acinetobacter* outbreak at Leiden University Medical Centre. (In fact, the authors stated that the data suggested that Bair Hugger blowers were "indeed the source of the outbreak.")
- The *Acinetobacter* outbreak could not be blamed on Bair Hugger because the filters were not changed on schedule. (In fact, dirty filters should further restrict airflow, reducing—rather than increasing—airborne contamination.)
- The study conducted by microbiologists at Stanford University was not scientifically valid. (The study selected for publication by the American Society of Anesthesiologists.)
- Arizant inexplicably defended itself against Dr. Beavers' "reservoirs of infection" statements by explaining that the article and speeches identified Bair Hugger blowers as only one of several "reservoirs of infection," not the only one.

After Hot Dog International provided proof to the German court regarding the accuracy of each statement, Arizant recast its claim as an objection to the manner in which Hot Dog International made its statements, not the underlying accuracy of the statements themselves.

More recently, a law firm representing Arizant threatened a British medical devices distributor with litigation if the distributor did not stop informing customers of the research relating to FAW. (Dechert letter at Annex G)

Rather than encourage scientific research concerning contaminated Bair Hugger blowers, Arizant seems to be attempting to thwart such research. Recently an employee of Arizant threatened Prof. Leaper with "repercussions" if revelations of the risks of

FAW did not cease. (Statement of Steve Hammant-Stacy, Annex H) In May, Arizant's vice-president of sales, Robert Buehler, contacted Prof. Leaper in England, offering financial assistance if Leaper would conduct research on behalf of Arizant. (Statement of Robin Humble, Annex I.) Shortly thereafter, Prof. Leaper notified his research team that he would not do any more research on FAW contamination or laminar flow disruption. (Affidavit of Dr. Scott Augustine, Annex F)

In 2009, on the eve of research to be conducted by doctors that would have tested the Bair Hugger blowers located at University Hospital in Caen, France for contamination, Arizant quickly removed every Bair Hugger blower in the facility and replaced them with 80 new blowers. At an approximate retail price of $1,400, this cover-up cost Arizant more than $112,000. (Id.) Similarly, just before UK orthopedic surgeon Dr. Mike Reed was to begin testing the contamination levels of Bair Hugger blowers at a National Health Service Hospital in Northumbria, Arizant replaced all the hospital's blowers with new (and, obviously, uncontaminated) units. Id.

E. Recommendations

Although MedWatch does not specifically provide for Reporters to make recommendations concerning safety improvements, I will nevertheless make suggestions throughout this report. As regards the bacterial contamination, I recommend:

1. As demanded by several clinical researchers, Arizant and other manufacturers should be required to place a HEPA filter on the hose-ends of FAW blowers. As described below, this action would also bring FAW blowers into conformity with operating room ventilation standards promulgated by the Hospital Infection Control Practices Advisory Committee of the National Center for Infectious Diseases ("HICPA").

In its 1999 "Guideline for Prevention of Surgical Site Infections," HICPA urged that inside operating theatres, hospitals should "filter all air, re-circulated and fresh, through the appropriate filters per the American Institute of Architects' recommendations."[13] That 1996 guideline was updated by the 2005 Standard 170, *Ventilation of Healthcare Facilities* produced by the American Society of Heating, Refrigerating and Air-Conditioning Engineers ("ASHRAE").

Standard 170 covers all equipment used for heating air in healthcare facilities. For inpatient surgery facilities, double filtration is required, as has been recommended by several Bair Hugger researchers. Filter bank No. 1 (inlet filtration) must achieve MERV 8 (40-50% efficiency) and filter bank No. 2 (outlet filtration) must achieve MERV 14 (90% efficiency). Moreover, at Sec. 5.7.2, the ASHRAE standard states:

All air distribution devices shall meet the following requirements:

a) Surfaces of air distribution devices shall be suitable for cleaning.

b) The supply diffusers in Class B & C surgeries shall be designed and installed to allow for internal cleaning.

2. FAW air-circulation systems should be required to meet all aspects of ASHRAE Standard 170, including those listed above. Since "internal cleaning" is impossible, however, both inlet and outlet filters should be HEPA. Otherwise, pathogens will continue to breed inside the blowers and be blown into the sterile field.

3. Contaminated blowers should be recalled from the field and decontaminated before being put back into service.

4. Warning labels should be required, identifying the risk of internal contamination.

II. Degradation of filtration

Two models of Bair Hugger blowers can be found in the field. In the United States and around the world, tens of thousands of the Model 505, introduced in the early 2000s, remain in use. The Model 750 blower became available a few years ago, and all new Bair Hugger blowers sold since by Arizant have been Model 750s.

A. Misrepresentations to the FDA

In an effort to obtain 510(k) clearance for its Model 750 blower, Arizant successfully established substantial equivalence between the Model 750 and its predecessor, the Model 505. In a communication received by the FDA on September 6, 2000 identified as K001149, Arizant represented to the FDA that the filtration of the Model 750 was "HEPA," an improvement over the " .2 micron filter" of the Model 505. (Annex J) The US Centers for Disease Control defines a HEPA (High Efficiency Particulate Air) filter as an air filter that removes more than 99.97% of particles 0.3 microns or larger.[14]

Until recently, the filtration efficiency of the Model 505 was 93.8%. As certified by an independent laboratory, however, replacement filters for the Model 505 have recently been reduced to 63.8 % efficiency. Similar testing revealed that the filter in the Model 750 blower achieves only 61.3% efficiency. (Annex K) The previously mentioned two studies conducted by Prof. Leaper's group (one of which has been accepted for publication by the *American Journal of Infection Control*) revealed average filtration efficiencies to be 61.3% and 63.8% respectively.

This degradation of filtration efficiency by Arizant apparently occurred after

Arizant's executives were informed of the contamination of their blowers at the October 2007 annual meeting of the American Society of Anesthesiologists. Arizant, however, had long known that inadequate filtration can lead to contamination of the surgical field. In a letter to the FDA regarding its cardiac FAW blanket received on June 26, 1997 identified as K964673, Arizant admitted that "air blown intraoperatively across the surgical wound may result in airborne contamination." (Annex L) Arizant successfully argued, however, that wound infections would be avoided because "[all] Bair Hugger Blankets designed for use in the operating room feature a tape barrier which prevent (sic) air from migrating toward the surgical site." Id.

While the statement regarding the universality of a tape barrier may have been true when made, it is true no longer. At least seven models of Bair Hugger blanket (generally called the "Underbody Series") do not even attempt to contain contaminated air within the taped edge of the blanket. Instead, they blow contaminated air directly toward the surgical field. [15] Also, my personal experience shows that the tape barrier frequently becomes dislodged during preparation for surgery.

Even Arizant's 1997 representation that the tape barrier could contain the contaminated air was erroneous. In fact, the hot air escapes near the floor, mixes with dirty air and rises (even against laminar flow) into the sterile field. (See video attached as Annex M and Section III, below.)

B. Other misrepresentations by Arizant

According to the Inadvertent Perioperative Hypothermia Costing Report prepared by the NHS's Purchasing and Supply Agency ("PASA") in the UK, a distinguishing feature among FAW devices is the "...presence of an air filter capable of removing very small (0.2-0.3 micron) airborn particles from the air drawn into the device, as an infection control measure."[16]

Based on this false belief, both NICE and MHRA have concluded that Bair Hugger blowers do not present a risk of infection. The false belief arises from representations by Arizant in its published Product Specifications that Bair Hugger filtration is "high efficiency" (HEPA) (Annex N) as well as direct representations to MHRA and PASA. As explained above, these representations are false. Moreover, former engineering and product development employees of Arizant have stated in an affidavit filed with the German court as follows:

- The inlet filtration of Bair Hugger blowers does not prevent contamination. The majority of blowers cultured were contaminated with bacteria.
- Some forced air blowers emit large numbers of 0.3-0.5 micron particles. Up to 50 million particles per hour blowing from the hoses have been measured.

- The warm, dry interior of forced air blowers does not kill all pathogens. (Annex O)

In 2008, after clinicians throughout the UK were informed by Dr. Augustine, the inventor of Bair Hugger therapy, of the risk of contamination created by FAW, Arizant's CEO, Gary Maharaj, wrote a widely disseminated letter, quoting a finding by NICE that "FAW systems are naturally built to eliminate bacteria." (Annex P). One can only assume that Maharaj knew the statement was inaccurate; he had been informed of the contamination problem in 2007. Moreover, a device with a filtration efficiency of 61.3% is barely built to reduce bacteria, much less "to eliminate bacteria."

In March 2010, Dr. Scott Augustine wrote Maharaj and Arizant's Chief Regulatory Officer, David Westlin, urging them to inform the FDA and European regulators of the contamination risk created by Bair Hugger blowers and to cease the fraudulent claims of HEPA filtration. (Annex Q). Arizant did not respond.

Arizant continues to make the same misrepresentations via the Internet. In a document on its website entitled, "Facts About Forced-Air Warming." Arizant purports to "address some inaccuracies about forced-air warming that makers of competing technologies are promoting." Once again, Arizant claims that Bair Hugger filtration is "high efficiency" (HEPA). (Annex R)

C. Regulatory consequences

As described in 21 CFR 807.81(a)(3), a new 510(k) application is required for changes to an existing device where the change could significantly affect the safety or effectiveness of the device. Arizant's failure to file a new 510(k) after downgrading its filter to 61.3% efficiency violates this standard.

The FDA requires that every modification to a device be reviewed by appropriate personnel in accordance with the 21 CFR 820 Quality System regulations. If the modification is determined to be insignificant, the decision must be documented with supporting data in the master file. If it is significant, a new 510(k) must be filed. Given the consequences of the degradation of the Bair Hugger filter, the change certainly required filing a new 510(k).

A proper analysis would have followed the protocols set forth in ISO Standard 14971, entitled "Medical devices — Application of risk management to medical devices." Sec. D.2.2.3 cites a situation exactly like that presented by Bair Hugger as an example of systemic fault:

> inadequate environmental control, or a breakdown in environmental control systems, leads to contamination with a

toxic substance or an infectious agent.

Sec. D.3 describes how to evaluate the level of risk. Given the often-catastrophic consequences of surgical infections, the following standard seems to apply:

> [F]or significant hazards, that is, hazards which could inflict harm of high severity…no level of exposure can be identified that corresponds to a risk so low that there is no need to bother about it. In such cases, the risk estimate should be made on the basis of a reasonable worst-case estimate of probability.

Since it did not file a new 510(k), Arizant either failed to perform a risk analysis at all or it performed the analysis inadequately. A calculation of Arizant's culpability should be influenced by Arizant's 1997 admission that "air blown intraoperatively across the surgical wound may result in airborne contamination" as well as by any financial gain that Arizant enjoyed as a result of the safety degradation.

Such culpability, in fact, could extend to illegal adulteration. Medical devices are subject to the adulteration provisions of Sec. 501 of the Food, Drug and Cosmetics Act. Specifically, Sec. 501(c) states that a device is adulterated if its quality falls below that which it purports or is represented to possess. Arizant represented to the FDA and to the public that the Model 750 Bair Hugger blower protected surgical patients from bacterial contamination with HEPA filtration. It then knowingly failed to meet that standard. Despite the degradation of safety, Arizant continues to claim high efficiency filtration. The FDA may assess monetary penalties for violations of Sec. 301(a) of the Act (the introduction or delivery "into interstate commerce of any … device … that is adulterated or misbranded") of up to $15,000 for each violation up to a total of $1,000,000.

D. Recommendations

Arizant should be required to restore the inlet filtration in its Bair Hugger blowers to HEPA standards. As noted above, an additional filter that conforms to ASHRAE Standard 170 should be installed distally at the hose end. Neither action, however, deals with the immediate issue: tens of thousands of Bair Hugger blowers that have become internally contaminated with pathogens because of the inadequate inlet filtration. All such blowers should be recalled from the field and be internally decontaminated before being put back into service.

III. Destruction of Laminar Flow protection

A. Importance of Laminar Flow

According to a study cited by the Centers for Disease Control, laminar flow ventilation reduces SSIs by more than 50%--from 3.4% to 1.6%. [17] In a study of 435 patients undergoing Austin Moore hemiarthroplasty, the rate of re-operation for all indications in the non-laminar airflow theater group was four times greater than in the laminar airflow group. Similarly, the use of laminar flow reduced infection rates after posterior spinal fusion.[18]

Laminar flow is especially important in orthopedic surgery—where a single airborne bacterium has been shown to be able to infect implanted foreign material such as a prosthetic knee or hip.[19] For that reason, current CDC recommendations include performing orthopedic implant operations under laminar flow.[20]

Similarly, a 2003 article by Farhad Memarzadeh, PhD, PE, chief of technical resources in the Division of Engineering Services at the National Institutes of Health, concluded:

> Systems that provide laminar flow regimes represent the best option for an operating room in terms of contamination control, as they result in the smallest percentage of particles impacting the surgical site.[21]

B. Impact of FAW on Laminar Flow

Observations during the above-cited research lead to concern about the impact of the "waste" hot air emitted from FAW blowers—particularly on laminar flow ventilation during ultra-clean surgery. In general, a FAW blower produces 1,000 watts of heat energy per hour. Only about 50 watts are transferred to the patient; the rest escapes from under the surgical drape near the floor, then rises through the dirty air located near the floor and into the laminar flow. The air then cools and dumps the contaminated air into the sterile field. (A visualization of this appears in the video attached as Annex M)

Similarly, this phenomenon can be observed in the blog[22] and YouTube videos[23] posted by Drs. Reed and McGovern – orthopedic surgeons and researchers in Northumbria, UK. In these experiments, they used "neutral buoyancy" bubbles (small soap bubbles filled with a mixture of air and helium which is adjusted to produce neutral buoyancy), to show the air currents created by rising waste heat from FAW.

Additional research regarding the destruction of laminar flow protection by waste heat from FAW blowers includes the following:

1.) "Forced Air Warming versus Conductive Fabric Warming – An Evaluation of Conventional (non-laminar, positive pressure) Operating Room

Ventilation Disruption," a recent study in submission for publication in the *Annals of Surgery*, was authored by a team including myself and Drs. M. Reed and P McGovern. The effect of waste heat was studied in a conventional (non-laminar, positive pressure) operating room ventilation environment. FAW was compared with conductive fabric warming (CFW), with and without a surgeon by the table. Tracer smoke was introduced near the floor under the operating table. The degree of ventilation penetration and disruption was determined by the percentage of smoke detected in the air directly above the surgical site. The results:

* With a surgeon present, forced air warming (FAW) on "high" heat resulted in a large increase in the percentage of tracer-laden air from under the operating table detected at the surgical site versus FAW ambient control (63.0% v 6.9%).
* With a surgeon present, conductive fabric warming (CFW) on "high heat" resulted in no increase in the percentage of tracer-laden air detected at the surgical site versus CFW ambient control (4.9% v 6.1%).
* The use of forced air warming was found to generate sufficient waste heat to disrupt conventional OR ventilation and mobilize tracer contaminated air from under the table upwards and into the surgical site. Detected particle counts showed that in the presence of a single surgeon, the waste heat from FAW on "high" could mobilize sufficient quantities of tracer-laden floor air, so that more than half of the air directly above the surgical site consisted of potentially pathogenic floor air. (Annex S)

2.) "Forced Air Warming versus Conductive Fabric Warming – An Evaluation of Laminar Operating Room Ventilation Disruption" a recent study in submission for publication in the *British Journal of Orthopedics*, was authored by a team including myself and Drs. M. Reed and P McGovern. We compared the effects of two patient warming modalities classified as having "low waste heat load" (conductive fabric warming - "CFW") and "high waste heat load" (forced air warming – "FAW") on laminar ventilation performance. Neutral buoyancy soap bubbles ("bubbles") were used to visualize airflows and particle counts of tracer smoke were performed 15 cm above the surgical site to quantitatively assess tracer mobilization into the surgical site. The results:

* Vented waste heat from FAW use at 43°C created warm-air convection currents that mobilized tracer particulate upwards against the downward laminar flow and into the surgical site, as indicated by bubbles.
* With no surgical staff, the use of FAW at 43°C resulted in a ≈30-fold increase in particle counts at the surgical site versus controls.
* With a surgical staff present, the use of FAW at 43°C resulted in a ≈90-fold increase versus controls.
* CFW use at 43°C produced minimal waste heat and had no effect on airflow currents or particle counts at the surgical site versus controls.

* Conclusion: The use of FAW generated sufficient waste heat to form convection currents that disrupted laminar ventilation performance and mobilized tracer contaminated air into the surgical site from high pathogenic-risk locations near the floor and under the drape. Bubbles showed the sheltered space between the surgeon's body and operating table as the primary area these convection currents form. (Annex T)

3.) In a abstract submitted to the American Academy of Orthopedic Surgeons 2011 annual meeting by Drs. M Reed and P McGovern, FAW was compared with conductive fabric blankets (CFB) in its effect on laminar flow ventilation. Airflow was visualized with neutral buoyancy bubbles introduced under a torso warming blanket at the head end of the table. The findings:

* There was no contamination of the surgical site when using CFB.
* A significant increase in laminar ventilation disruption was detected using Poisson regression for FAW v CFB with no ether screen (6 v 0 bubbles over the surgical site; $p<0.01$).
* A very significant increase in laminar ventilation disruption was detected using Poisson regression for FAW v CFB with a half height ether screen (146 v 0 bubbles over the surgical site; $p<0.01$).
* FAW disrupts laminar ventilation performance and mobilized potentially contaminated under-drape air against the downward laminar flow and into the surgical site.

C. Arizant's knowledge of the risk

In October 2009, at the annual meeting of the American Society of Anesthesiologists held in New Orleans, Arizant was informed of the disruption of laminar flow protection caused by the waste hot air exhausted by Bair Hugger blowers. The video (Annex M) was watched several times by Arizant Chief Scientist Al Vanduren, whose comments included, " I didn't know that," and "I didn't think the air would do that." Other Arizant executives watched the video as well. (Affidavit of Scott Augustine, Annex F)

D. Arizant's response

Ignoring its own observations and scientific evidence to the contrary, Arizant's webite assures clinicians that the contaminated air cannot reach the surgical site because, "Air velocity within the operating theatre is many times stronger than that of the forced-air warming blanket." (Annex R)

Arizant has even begun running advertisements in UK medical publications, further attempting to obfuscate the issue. (Annex U). In response to concerns that waste

hot air from Bair hugger blowers disrupts the protection of laminar flow, Arizant's advertisement states:

> While simple logic makes it clear that forced air warming has no impact on laminar conditions, science also supports this. A forced air warming blanket delivers less than one percent of the airflow of a laminar flow system and therefore is unable to affect laminar flow ventilation systems." (Emphasis added) (Id.)

If disruption of laminar flow were a mere marketing issue, Arizant's misdirection might be acceptable, perhaps even clever. The issue, however, is patient safety, and Arizant has an obligation to be honest rather than clever. A comparison of airflow is irrelevant. The fundamental issue is waste heat, not waste air. The physics are simple: heat rises. Almost all of the 1000+ watts of heat/energy generated by the Bair Hugger blower escapes near the floor, mixes with dirty air, rises into the laminar flow and falls into the sterile field. (Annexes M and T).

E. Additional evidence

Other recent evidence adds to the concerns about airborne contamination during surgery. For example, in one of a series of articles published in *Interface*, the Journal of the UK's Royal Society, researchers wrote:

"In hospital operating theatres, the convective flows could spread infection and pose a real threat to the outcome of surgery." [24]

Finally, a Ph.D. dissertation published by University Of Leeds engineering student Katherine A. Roberts under the supervision of surgical air-quality expert Prof Clive Beggs investigated the likelihood of airborne dissemination of *Clostridium difficile*. She stated that " the aerial dissemination of *C. difficile* in hospitals contributes to the spread of disease, accompanied by the contact route." [25]

Her conclusion:

> The evidence for the aerial dissemination of *C. difficile* discussed in this thesis suggests that the high rates of CDI experienced in UK hospitals and around the globe may be due to the aerial dissemination route increasing environmental contamination. Id.

Although the evidence that FAW spreads *C. difficile* is far less developed than

evidence regarding other pathogens, Roberts's conclusion underlines the importance of protecting surgical patients from aerosolized bacteria.

E. Recommendations

Unlike the previous issues raised in this Report, the destruction of the protection of laminar flow ventilation by waste heat has no easy solution. Waste heat is an inescapable by-product of FAW. At a minimum, therefore, the FDA should require that the labels and instructions for FAW blowers contraindicate their use in orthopedic implant and other ultra-clean surgeries employing laminar flow protection.

IV. Violation of reprocessing standards

A. Contaminated blowers placed in hospitals

Of the tens of thousands of Bair Hugger blowers loaned (or leased without charge) to US hospitals, many thousands have been refurbished or remanufactured by Arizant. That is, after several years of use, the units were returned to Arizant for repair, were refurbished, then returned to the field for use in other hospitals with their serial numbers prefaced with an "R." (Affidavit of Dr. Scott Augustine, Annex F)

Remanufacturing and refurbishment at Arizant includes replacing filters and hoses, checking electronics and cleaning the exterior of the blower as needed. The interior air-flow path of the blower, however, is not cleaned. In fact, without complete disassembly of the device, it cannot be cleaned. Id. The obligation of a re-manufacturer, however, is to return the medical device to its original specifications. 21 CFR 820 In this case, it certainly requires that Arizant clean the contaminated interior of the devices.

Upon original placement in the field, the air-flow path of a Bair Hugger blower is clean and uncontaminated. As studies funded by Arizant have shown, such pristine blowers do not add to the bacterial load in operating theatres. However, the research cited herein establishes that after significant use, the airflow paths of the blowers become heavily contaminated with pathogens.

Arizant places refurbished, but contaminated, FAW blowers in operating theatres as if they were new. The hospitals' biomedical engineers, having no way to check the cleanliness of the sealed interior of the blowers, certify them for use. In this manner, pathogenic contamination from one hospital can spread to others.

B. Recommendation

All refurbished "R" Bair Hugger blowers should be recalled from the field and be internally decontaminated. If internal decontamination is not possible, use of refurbished blowers should be prohibited.

V. Failure to Meet FDA Reporting Obligations

A. Arizant's failure to file an MDR

The FDA requires that a manufacturer report via the Medical Device Reporting (MDR) system when the manufacturer becomes aware of information reasonably suggesting that one of its marketed devices has malfunctioned and that such malfunction has or would be likely to contribute to a serious injury. 21 CFR Sec. 803.3(q) A malfunction is a failure of the device to meet its performance specifications or to otherwise perform as intended. 21 CFR Sec. 803.3(m) A malfunction is reportable if it compromises the device's therapeutic effectiveness or if it could contribute to a serious injury or a significant adverse device experience. Id. A device may have contributed to such an event, among other reasons, because of improper or inadequate device design. 21 CFR Sec. 803.3(d) A manufacturer has become aware of a reportable event when a person with management or supervisory responsibilities becomes aware of the event from any source. 21 CFR Sec. 803.3(c)

Even if unaware previously, Arizant learned that its blowers spread pathogenic contamination no later that October 2007, at the annual meeting of the American Society of Anesthesiologists. Arizant learned that waste heat from its blowers destroys the protection of laminar flow and dumps dirty air into the surgical field no later than October 2009, again at the same annual meeting. All of these facts, as well as published peer-reviewed evidence, were reiterated in Dr. Augustine's letter to Arizant CEO Gary Majaraj dated April 2, 2010.

Despite this information, Arizant has not filed an MDR or provided any other information to the FDA. Presumably, Arizant will defend its inaction by noting that no hospital has reported a surgical infection traced specifically to a contaminated Bair Hugger blower.

Such, however, is not the standard. As noted above, a malfunction is reportable if it could contribute to a significant adverse experience. Destroying the protection of a surgical laminar flow system is a significant adverse device experience even if no infection occurs. In orthopedic implant surgery contamination by a single bacterium can lead to infection.[26] With such a risk, Arizant's awareness that Bair Hugger systems do not meet their own filtration specifications and blow millions of particles into the surgical field certainly created a reporting obligation. The failure to report is a

prohibited act, and renders the device misbranded. FDCA §§ 301(q)(1), 502(t), 21 U.S.C. §§ 331(q)(1), 352(t)

Given that the FDA cited Arizant with Form FDA 483 in January 2010 for failing to properly report injuries, the company should be acutely aware of its responsibilities under the MDR system. (Annex V)

B. Recommendation

Arizant should incur the full penalties that can be levied by the FDA for its repeated failure to report risks to patient safety.

Conclusion:

I request that the FDA carefully review the evidence attached and fully investigate the issues raised. If the FDA confirms the accuracy of the facts and analysis I have provided, I ask that the FDA act quickly to protect vulnerable surgical patients, particularly those undergoing orthopedic or other ultra-clean surgery.

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